Atty. Docket No.: 101328-243 Examiner: Bhisma Mehta

REMARKS

The pending Office Action addresses claims 1-27. Claims 3-20 and 23-27 were previously withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a nonelected invention. Applicants maintain the right of rejoinder of any and each of the withdrawn claims and full examination for patentability under 37 CFR § 1.104. Claims 1, 2, 21, and 22 remain rejected. Reconsideration of the rejection of claims 1, 2, 21, and 22 is respectfully requested in view of the following remarks.

At the outset, Applicants would like to thank the Examiner for the courtesy of an interview on February 25, 2009, with the undersigned attorney and attorney Thomas J. Engellenner for Applicants. During the interview, U.S. Patent No. 6,010,478 of Bellhouse et al. was discussed, and Applicants explained the differences between Bellhouse and the claimed invention. Agreement was reached that the arguments made during the interview and the claim amendments submitted herewith would likely overcome the present rejection.

Amendments to the Claims

Applicants amend claim 1 to clarify that the microconduit formed by scissioning the tissue is used for manipulation or modification of the body tissue in a manner selected from a number of different methods recited in the Markush group. Claims 21 and 22 are amended to agree with claim 1. Support for these amendments can be found throughout the specification. No substantive effect is intended by these amendments, and these amendments are not made for the purpose of overcoming the present rejections.

Applicants also add new claims 28 and 29, which are both directed to the velocity of the plurality of microparticles. Claim 28 recites a velocity that is approximately less than 200 meters per second and claim 29 recites a velocity that is approximately less than or equal to 1 meter per second. Support for these claims can be found throughout the specification, for example at paragraph [0055] of the published application.

No new matter is added.

Rejections Pursuant to 35 U.S.C. § 102(e)

The Examiner rejects claims 1 and 2 pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,010,478 of Bellhouse et al. ("Bellhouse"). The Examiner argues that Bellhouse discloses a method of modifying or manipulating body tissue as recited by Applicants. The Examiner also argues that Bellhouse teaches treating an infection by delivering a therapeutic molecule or ion through the tissue. Applicants respectfully disagree.

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As discussed during the interview, the method recited in independent claim 1 requires that tissue be *scissioned* by way of a plurality of microparticles to form a *microconduit*, and subsequently, that the microconduit be used to manipulate or modify the body tissue in a variety of ways. With respect to the elected species, the method includes directing at least one therapeutic molecule or ion into the microconduit to treat an infection below the surface of the body tissue. The step of administering at least one therapeutic molecule is distinct from the step of forming a microconduit by scissioning.

Bellhouse, on the other hand, propels its particles (P) toward the target surface at velocities sufficient for the transdermal delivery of the particles across skin or mucosal tissue. (Col. 9, lines 10-20.) Bellhouse does not disclose scissioning the tissue with microparticles to form microconduits nor achieve directing therapeutic molecules into the microconduits for treatment purposes.

Accordingly, claim 1, as well as claims 2 and new claims 28 and 29 which depend therefrom, represents allowable subject matter.

Claims 28 and 29 are further distinguishable from Bellhouse because Bellhouse fails to disclose the delivery of microparticles at a velocity that is approximately less than 200 meters per second or at a velocity that is approximately less than or equal to 1 meter per second. In fact, Bellhouse *teaches away* from delivery of particles at such speeds because Bellhouse relies on a "supersonic delivery" in the range from about 200 to about 3000 meters per second. (*See* col. 10, lines 17-35; *see also* col. 7, lines 36-43.)

Accordingly, claims 28 and 29 represent additional allowable subject matter.

Rejections Pursuant to 35 U.S.C. § 103(a)

The Examiner rejects claims 21 and 22 pursuant to 35 U.S.C. § 103(a) as being obvious over Bellhouse in view of U.S. Patent No. 5,947,956 of Karell et al. ("Karell"). The Examiner argues that

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Bellhouse discloses the method substantially as claimed, but is silent on the microconduit being formed through nail tissue and administering at least one therapeutic molecule or ion into at least one microconduit through nail tissue. The Examiner relies on Karell to remedy the deficiencies of Bellhouse stated by the Examiner. Karell, which is directed to a microsurgical laser unit for performing surgery on nails, fails to remedy any of the aforementioned deficiencies of Bellhouse. Karell fails to teach or even suggest *scissioning* tissue with microparticles and then directing separate therapeutic molecules toward the target surface for treatment. At least because Karell fails to remedy the previously discussed deficiencies of Bellhouse, claims 21 and 22 represent allowable subject matter in view of both Bellhouse and Karell.

Rejoinder

Because independent claim 1 is believed to be in condition for allowance and such claims are generic to species identified in the restriction requirement, rejoinder of claims 3-20 and 23-25 is also requested.

Conclusion

Applicants submit that all pending claims are in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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